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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,965	11/06/2000	Esmail Kiani-Azarbayjany	MLABS.018C3	8509

20995 7590 10/10/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/10/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706,965

Applicant(s)

KIANI-AZARBAYJANY ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/2003 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,372,135 to Mendelson et al. Mendelson et al. discloses a system for obtaining glucose information. (column 1, lines 19-22 of Mendelson et al.). The system includes a lamp (10) that emits a plurality of wavelengths, a pulse inducement device (26, 26'), a detector (32, 32'), and a signal processor (36). (Figs. 3 and 5 of Mendelson

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et al.). In regard to claim 12, the pulse inducement device is operated in a periodic manner which would cause periodic changes in the volume of blood. (column 6, lines 11-15 of Mendelson et al.).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,372,135 to Mendelson et al. as applied to claim 1, and further in view of U.S. Patent 4,883,055 to Merrick. Mendelson et al. teaches that the pulse inducement device causes periodic changes in the volume of blood. (column 6, lines 11-15 of Mendelson et al.). Mendelson et al. does not teach what kind of periodic function to use with the pulse inducement device. Merrick teaches a pulse oximeter which analyzes the oxygen saturation of blood. Merrick discloses that applying pressure which is synchronized with the normal blood pulse is useful for analyzing blood constituents. (column 2, lines 38-40 of Merrick). Such a periodic function falls within the scope of the type of periodic function as suggested by Mendelson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a periodic function that is synchronous with the normal pulse rate as disclosed by

Merrick in the pulse inducement device of Mendelson et al. since Mendelson et al. suggests that the pulse inducement device may be used in a periodic manner and Merrick teaches one such periodic manner. In regard to claim 14, Mendelson et al. does not teach the use of a receptable that receives the fleshy medium having an inflatable bladder. Mendelson et al. teaches that the pulse inducement device can be an electro-mechanically squeezing head or clamp. (column 5, lines 60-63 of Mendelson et al.). Mendelson et al. further teaches that the modulation of blood volume can be accomplished in a number of ways. (column 4, lines 32-34 of Mendelson et al.). Mendelson et al. is implying that various methods can be used as the pulse inducement device. Merrick teaches an inflatable bladder that is used as a pulse inducement device. (Figs. 1-2 of Merrick). Such a device falls within the scope of the devices for creating blood flow modulation as suggested by Mendelson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the inflatable bladder of Merrick as the pulse inducement device of Mendelson et al. since Mendelson et al. implies that various electro-mechanical devices can be used for blood flow modulation and Merrick teaches one such device.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,372,135 to Mendelson et al. as applied to claim 1, and further in view of U.S. Patent 5,007,423 to Branstetter et al. In regard to claim 15, Mendelson et al. does not teach the use of a receptable that receives the fleshy medium having a temperature variation element for inducing the change in blood flow. Mendelson et al. teaches that

the modulation of blood volume can be accomplished in a number of ways. (column 4, lines 32-34 of Mendelson et al.). Mendelson et al. is implying that various methods can be used as the pulse inducement device. Branstetter et al. teaches a temperature element for increasing the blood flow. (column 2, lines 32-47 of Branstetter et al.). Such a device falls within the scope of the devices for creating blood flow modulation as suggested by Mendelson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the temperature element of Branstetter et al. as the pulse inducement device of Mendelson et al. since Mendelson et al. implies that other devices can be used to induce blood flow modulation and Branstetter et al. teaches one such device. The pulse inducement device is operated in a periodic manner. (column 6, lines 11-15 of Mendelson et al.).

Response to Amendment

7. The declaration filed on 7/31/2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Mendelson et al. reference. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Mendelson et al. reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). "The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention

claimed or something falling within the claim.” (See MPEP 715.02). The evidence that was submitted to show conception discloses the use of a pulse-inducing device while taking venous blood saturation measurements. The claimed invention of the present invention is the use of a pulse-inducing device for making glucose measurements. The evidence to prove conception must show a glucose-measuring device comprising a pulse-inducing device, a light source, and optical detector to establish possession of the claimed invention. It is noted that the evidence that was submitted shows an invention already known in the art, i.e., a pulse-inducement device used in saturation measurements, as shown in U.S. Patent 4,883,055 to Merrick. The evidence submitted is also insufficient to establish diligence from a date prior to the date of reduction to practice of the Mendelson et al. reference to either a constructive reduction to practice or an actual reduction to practice. “Where conception occurs prior to the date of the reference, but reduction to practice is afterward, it is not enough merely to allege that applicant or patent owner had been diligent.” (See MPEP 715.07(a)). The Applicant has provided no evidence indicating due diligence between the date prior to 12/31/1991 and the filing date of 6/7/1995.

Response to Arguments

8. Applicant's arguments filed 7/31/2003 have been fully considered but they are not persuasive. The Examiner agrees with the Applicant that Mendelson et al. does not claim a system for monitoring concentrations of blood constituents using an active inducement device, which causes periodic changes in a volume of blood in the fleshy


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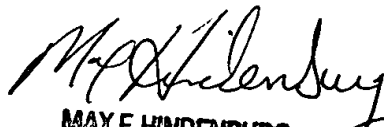
medium. As a result, a 37 CFR 1.132 declaration would overcome the Mendelson et al. reference but because the declaration that was submitted was insufficient as indicated above, the rejections under 102 and 103 using the Mendelson et al. reference are properly maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Matthew Kremer
Assistant Examiner
Art Unit 3736


MAX E. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700